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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,250	11/30/2001	Shoukat Dedhar	KINE001CIP5	5685

24353 7590 03/08/2004

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EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/998,250

Applicant(s)

DEDHAR ET AL.

Examiner

Theodore J. Criares

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**CLAIMS 1, 2, 4-10, 13 AND 14 ARE PRESENTED FOR**  
**EXAMINATION**

Applicant's arguments filed August 28, 2003 have been fully considered but they are not persuasive. Applicants argue that:

1. undue experimentation would not be necessary in obtaining the compounds as claimed;
2. screening programs have shown results in identifying compounds of 6,214,813 and 6,291,447 .
3. 6,001,622 which teaches the compound "wotmannin" has activity in the treatment of psoriasis, a cutaneous inflammation; and
4. Data has been presented that psoriasis can be treated.

***Effective Priority Date***

The present application has a filing date of November 30, 2001, although it claims the benefit of parent applications and Provisional Application 60/009,074 filed December 21, 1995. This application is a Continuation-in -Part of SN 09/390,425 filed September 3, 1999 and now U.S. Patent 6,338,958.

However, the parent and provisional applications neither teach nor disclose the treatment of cutaneous inflammation with applicants' "small organic molecule" which blocks ILK activity.

Therefore, this applications filing date of November 30, 2001 controlled the examiners review of the subject application..

Art Unit: 1617

The rejection under 35 U.S.C. 112, first paragraph is maintained since the only compounds disclosed as of the filing of date of the present application are wortmannin and LY294002. These two agents, although taught in the parent applications were taught to block ILK activity, the applicants had no knowledge that these compounds would treat cutaneous inflammation as of the filing date of this application.

Therefore, applicants' arguments are unpersuasive since there was a lack of knowledge in the parent applications that compounds that block ILK can also be used to treat cutaneous inflammation, e.g., psoriasis. For example, Zhang et al (6,214,813) cited by applicants in their remarks neither identifies the compounds as small organic molecules nor is it taught therein that the compounds when administered treat psoriasis

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 13 and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Applicants' admissions in the remarks of August 26, 2003, Andersen et al (6,291,447) and Natarajan et al. (6,046,224). Applicants admit at page 5, of the remarks that Andersen et al. teaches the compounds within the scope of their claimed invention. However, the filing date of Andersen et al. is February 26, 1999. This reference also teaches at column10, lines 59 to 67 that the compounds taught therein can be administered to treat psoriasis.

Art Unit: 1617

An example of applicants' claimed compounds is LY294002 as taught at page 5, paragraph 18 of the specification. Natarajan et al. At column 10, lines 19-26, in Example teach the use of this compound as a PI-3 kinase inhibitor which establishes as a compound useful in the treatment of psoriasis as it is related to 12(s)-HETE (SEE Example 7) and column1, lines 15-26 which discloses the relationship of 12-(s)-HETE to the treatment of psoriasis. Therefore, this reference teaches the administration of one of applicants' known compounds in the treatment of psoriasis. It is to be understood that LY294002 is a small organic molecule.

That the claims are drawn to a biological pathway, i.e.. "a small organic molecule" that blocks ILK activity and similar language in claims 13 and 14 does not render the claims patentable since the mechanism would be inherent in the administration or any of the compounds of Andersen et al. or Natarajan et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1617

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admissions at page 5, penultimate paragraph, Andersen et al. and Natarajan et al.

The references set forth teach the use of compounds within applicants' claims to treat psoriasis. The difference between applicants' claims and the references is that the references fail to teach each of the each of the second therapies for the treatment of psoriasis. However, one of ordinary skill in the art would have been motivated to use these secondary therapies since they are well known to the art as admitted by the applicants at page 6, paragraph 23 of the specification.

Claim 8 is rejected since it reads on canceled claim 3.

None of the claims are allowed.

Applicant's amendments that amended the claims to cutaneous inflammation and disclosing compounds within applicants' claims necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

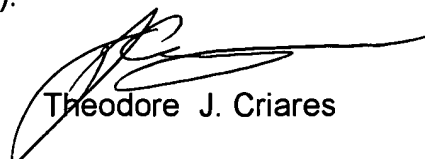
Art Unit: 1617

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Theodore J. Criares

Application/Control Number: 09/998,250

Page 7

Art Unit: 1617

Primary Examiner  
Art Unit 1617

TJC  
3/01/04